



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2000–P–0102 (formerly 2000P-1275), FDA–2000–P–0133 (formerly 2000P-1276), and FDA–2006–P–0033 (formerly 2006P-0316)]

Health Claim; Phytosterols and Risk of Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of enforcement discretion.

SUMMARY: The Food and Drug Administration (FDA) is extending the period of time that it intends to exercise enforcement discretion concerning the use of the health claim for phytosterols and risk of coronary heart disease (CHD), in a manner that is consistent with FDA’s February 14, 2003, letter of enforcement discretion to Cargill Health and Food Technologies, until publication of a final rule.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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240-402-1450.

SUPPLEMENTARY INFORMATION:

For the reasons described herein, FDA intends to continue to exercise enforcement discretion with respect to the use of a health claim regarding reduced risk of coronary heart disease (CHD) for phytosterol-containing conventional food and dietary supplements, in a manner that is consistent with FDA's February 14, 2003, letter of enforcement discretion to Cargill Health and Food Technologies, until publication of a final rule.

I. Regulatory History

In the Federal Register of September 8, 2000 (65 FR 54686), FDA issued an interim final rule (IFR) authorizing a health claim for plant sterol/stanol esters and CHD. Among other requirements, we established in the IFR that spreads and dressings for salads must contain at least 0.65 grams (g) of plant sterol esters per reference amount customarily consumed (RACC) to be eligible to bear the health claim and that spreads, dressings for salad, snack bars, and dietary supplements in soft gel form must contain at least 1.7 g of plant stanol esters per RACC to be eligible to bear the health claim.

FDA received a letter, dated January 6, 2003, from Cargill Health and Food Technologies requesting that FDA issue a letter stating its intention not to enforce certain requirements in the IFR. The letter cited new scientific evidence and comments submitted to FDA in the plant sterol/stanol esters health claim rulemaking in support of extending the authorized health claim to all forms and sources of phytosterols and product forms that might effectively reduce blood cholesterol levels. In response to the letter submitted by Cargill and other comments received to the IFR, we issued a letter of enforcement discretion on February 14, 2003 (the 2003 letter) (Ref.

1). In the letter, we explained that we would consider exercising enforcement discretion, pending publication of the final rule, with respect to certain requirements of the health claim. Specifically, we stated we would consider such discretion with regard to the use of the claim in the labeling of a phytosterol-containing food, including foods other than those specified in § 101.83(c)(2)(iii)(A) (21 CFR 101.83(c)(2)(iii)(A)), if: (1) The food contains at least 400 milligrams (mg) per RACC of phytosterols; (2) mixtures of phytosterol substances (i.e., mixtures of sterols and stanols) contain at least 80-percent beta-sitosterol, campesterol, stigmasterol, sitostanol, and campestanol (combined weight); (3) the food meets the requirements of § 101.83(c)(2)(iii)(B) through (c)(2)(iii)(D); (4) products containing phytosterols, including mixtures of sterols and stanols in free (non-esterified) forms, use a collective term in lieu of the terms required by § 101.83(c)(2)(i)(D) in the health claim to describe the substance (e.g., “plant sterols” or “phytosterol”); (5) the claim specifies that the daily dietary intake of phytosterols that may reduce the risk of CHD is 800 mg or more per day, expressed as the weight of free Phytosterol; (6) vegetable oils for home use that exceed the total fat disqualifying level can bear the health claim along with a disclosure statement that complies with § 101.13(h); and (7) the use of the claim otherwise complies with § 101.83. Thus, the 2003 letter described intended enforcement discretion with respect to: (1) Different forms and mixtures of phytosterols in a wider variety of products and (2) the use of the claim on foods containing lower levels of phytosterols than set forth in the IFR.

In the Federal Register of December 8, 2010 (75 FR 76526), we published a proposed rule that, if finalized, would amend § 101.83 (the 2010 proposed rule). The 2010 proposed rule, in part, responds to a health claim petition we received on May 5, 2006, and it also includes the evaluation of new scientific data that was not available when we published the IFR.

We stated in the 2010 proposed rule for phytosterols and the risk of CHD health claim that, pending publication of a final rule, FDA intends to consider the exercise of its enforcement discretion on a case-by-case basis when a health claim regarding phytosterols and CHD is made in a manner that is consistent with the proposed rule (75 FR 76526 at 76546).

The 2010 proposed rule also stated that, beginning 75 days after the date of publication of the proposed rule (February 21, 2011), FDA did not intend to exercise its enforcement discretion based on the 2003 letter (75 FR 76526 at 76546). We stated that starting on February 21, 2011, all products bearing the health claim would have to be in compliance with § 101.83, or if health claims were made in a manner consistent with the proposed rule, we would consider exercising enforcement discretion pending publication of a final rule.

In the 2010 proposed rule, we proposed to make several changes to the requirements for the nature of the food eligible to bear the claim that differ from the requirements in current § 101.83 and from the basis for enforcement discretion in the 2003 letter. Among other changes, FDA proposed to increase the amount of phytosterols that must be present in the food product from 0.4 to 0.5 g of phytosterols per RACC and to only allow the use of the claim in dietary supplements containing the esterified form of phytosterols. In addition, we proposed that a conventional food would be eligible to bear the claim if it is the subject of a GRAS notification to which FDA had no further questions.

After publication of the proposed rule, we received requests from industry to extend the 75-day period from the date of publication of the proposed rule for the exercise of FDA enforcement discretion based on the 2003 letter. We subsequently issued a notice in the Federal Register of February 18, 2011, extending the period during which we intended to exercise

enforcement discretion based on the 2003 letter to February 21, 2012 (76 FR 9525) (the February 18, 2011 notice).¹

In the February 18, 2011 notice, FDA stated that it intended to exercise enforcement discretion until February 21, 2012, with respect to the use of a claim regarding reduced risk of CHD in the labeling of a phytosterol-containing food, including foods other than those specified in § 101.83(c)(2)(iii)(A), based on the factors set forth in the 2003 letter for the use of such claim in the labeling of food. FDA also stated that the February 18, 2011 notice did not change how we intend to consider exercising our enforcement discretion when claims are made consistent with the proposed requirements in the proposed rule, and that our decision to extend the period of time during which we would consider the exercise of our enforcement discretion only related to FDA's enforcement discretion based on the 2003 letter.

II. Current Extension Of Intent To Exercise Enforcement Discretion

Since publication of the February 18, 2011, notice, we have received two additional petitions; one requesting an administrative stay of action with an embedded citizen petition and the other requesting an administrative stay of action. Each of the requests for an administrative stay of action concern FDA's use of enforcement discretion related to labeling of dietary supplements, pending the publication of a final rule.² In addition, FDA received numerous

¹ In the February 18, 2011, notice, we identified two letters (from the Council for Responsible Nutrition and the Consumer Healthcare Products Association) and two petitions for an administrative stay of action (from Cargill, Inc., and Pharmachem Laboratories, Inc.). These two petitions are under FDA consideration and neither the February 18, 2011 notice, nor this notice, represents a decision on the petitions, in whole or in part.

² FDA received a petition for an administrative stay of action with an embedded citizen petition from Pharmavite LLC ("Pharmavite petition") dated February 24, 2011, and a petition for an administrative stay from Botanical Laboratories, Inc. ("Botanical petition"), dated March 18, 2011 (Docket Nos. FDA-2000-P-0102, FDA-2000-P-0133, and FDA-2006-P-0033). Specifically, Pharmavite LLC requests FDA to stay its February 18, 2011, decision to discontinue enforcement discretion for dietary supplements containing free phytosterols that have been shown, through an adequate and well-controlled clinical trial, to reduce low density lipoprotein (LDL) and total cholesterol, pending publication of a final rule for the health claim. In a citizen petition embedded in the petition for an administrative stay, Pharmavite LLC also asked us to agree that: (1) A dietary supplement produced by Pharmavite LLC has been shown to effectively reduce LDL and total cholesterol; (2) FDA will continue to exercise enforcement discretion to permit this dietary supplement to bear an appropriately worded claim pursuant to the 2010

comments on the 2010 proposed rule requesting that FDA extend the period of enforcement discretion based on the 2003 letter until publication of a final rule. FDA has received new scientific data and information, through comments to the 2010 proposed rule, or submitted with petitions, relating to several of the factors we set forth in the 2003 letter, e.g., the possible health benefit of free phytosterols in dietary supplements and the minimum daily consumption amount of phytosterols necessary to achieve the claimed effect. We are reviewing the comments and information we received and do not intend to make a determination as to the daily phytosterols consumption amount needed to achieve the claimed effect or the eligibility of dietary supplements containing free phytosterols to bear the authorized health claim until the publication of the final rule.

Based on the new data and information currently under our review that may be important, to our consideration in deciding what requirements to include in the final rule, and the need to focus FDA's resources on other public health priorities, we find it appropriate to continue to extend our consideration of the exercise of enforcement discretion for the labeling of foods, including dietary supplements, bearing a health claim regarding phytosterols and risk of CHD consistent with the 2003 letter, until publication of the final rule.

Therefore, FDA is extending the period during which it intends to exercise enforcement discretion, consistent with the factors set forth in the 2003 letter, until publication of a final rule for the phytosterols and risk of CHD health claim. This document does not change how FDA intends to consider exercising its enforcement discretion when claims are made consistent with

proposed regulation, pending publication of a final rule addressing the health claim; and (3) the final rule will allow those dietary supplements containing free phytosterols that have been shown through an adequate and well-controlled clinical trial to effectively reduce LDL and total cholesterol to bear the claim. Botanical Laboratories, Inc., requested that FDA stay its February 18, 2011, decision to discontinue enforcement discretion for dietary supplements containing phytosterols in liquid form until the issuance of a final rule for the health claim. We are currently considering these petitions. This document does not represent a decision on these petitions, in whole or in part.

the proposed requirements in the proposed rule. Food, including dietary supplements, bearing the health claim would be required to comply with any revised requirements established in the final rule when the final rule becomes effective.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. Center for Food Safety and Applied Nutrition, Food and Drug Administration, Letter of Enforcement Discretion from FDA to Cargill Health & Food Technologies, Docket No. FDA–2000–P–0102, document ID DRAFT– 0059 (formerly 2000P–1275/LET3) and Docket No. FDA–2000–P–0133, document ID DRAFT–0127 (formerly 2000P–1276/LET4), February 14, 2003.

Dated: February 15, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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